

REMARKS

In the Official Action of October 27, 2005, Claims 1-16 are pending. The Examiner has made the restriction requirement final. Thus, Claims 5-12 and 14-16 have been withdrawn from further consideration as drawn to a non-elected subject matter.

This Response addresses each of the Examiner's rejections. Applicant therefore respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 1-4 and 13 are rejected under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter. The Examiner is of the opinion that the single amino acid modification of proteins recited in Claims 1-4 and 13 can occur spontaneously *in vivo*. Thus, the Examiner alleges that the proteins of Claims 1-4 and 13 may have the same characteristics and utility as proteins found naturally and therefore does not constitute patentable subject matter. The Examiner states that a new utility of the proteins can be evidenced by an increased purity. The Examiner suggests that presenting such evidence and amending the claims to recite the essential purity of the claimed products can obviate this rejection.

Applicant respectfully submits that the amino acid residue "Ile" having an aliphatic side chain is hydrophobic in nature, while the amino acid residue "Thr" having a hydroxy group in its side chain is hydrophilic and reactive. Thus, residues Ile and Thr have different properties. Applicant respectfully submits that a substitution of Ile with Thr in an amino acid sequence of a protein is therefore extremely rare in nature, especially in view of the tertiary structure of the protein. Thus, Applicant submits that without the hand of man, it is almost impossible in nature for a single substitution of Ile with Thr in the amino acid sequence of a protein at a specific site to be created without other mutations in the same amino acid sequence.

Applicant submits that in the absence of the effort of the present inventor, it would be almost impossible in nature to change Asn₁₀₆ to Ile₁₀₈ to Asn₁₀₆ to Thr₁₀₈ in the amino acid sequence of chicken cystatin and then to N-glycosylate the Asn₁₀₆.

Additionally, in the absence of the effort of the inventor, it could not be found that the Asn₁₀₆-glycosylated recombinant chicken cystatin has improved stability in a freezing-thawing process and in a heating process, and such prior to our present invention utility was not taught or suggested in prior art.

Regarding the purity of the Asn₁₀₆-glycosylated recombinant chicken cystatin, Applicant respectfully submits that the claimed recombinant chicken cystatin is purified, as evidenced by the specification on page 8, lines 20 to 23 and Figure 1, lanes C, D and E.

However, in an effort to favorably advance the prosecution and in consideration of the Examiner's suggestion, Applicant has also amended Claim 1 to incorporate the embodiment of Claim 2 and canceled Claim 2. Claim 1, as amended, recites "[A]n isolated N-glycosylation-modified recombinant chicken cystatin, characterized in that Asn₁₀₆ to Ile₁₀₈ in its amino acid sequence is modified to Asn₁₀₆ to Thr₁₀₈, and wherein the isolated N-glycosylated recombinant chicken cystatin has improved stability in a freezing-thawing process and in a heating process." Applicants respectfully submit that the properties of purification and improved stability of the claimed isolated protein evidences the hand of man, i.e., constitutes statutory patentable subject matter under 35 U.S.C. § 101.

Accordingly, the rejection of Claims 1-4 and 13 under 35 U.S.C. §101 is overcome and withdrawal thereof is respectfully requested.

Claim 13 is rejected under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite for reciting the phrase "compatible protein."

Applicant respectfully submits that an expander recited in Claim 13 is well known in the art as any type of colloidal substances (such as dextran) of high molecular weight used as a blood or plasma substitute for increasing the blood volume. See, e.g., the Medical Dictionary by U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894 (online version can be accessed at <http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>). Applicant further submits that a "compatible protein" or "compatible proteins" are well known in the art to be used as carrier solutions, e.g., fetal calf serum, maternal serum, or human albumin fraction. Applicant submits that a "compatible protein" that is added to surimi as recited in Claim 13 has been well known and conventionally used in the art, such as soybean powder. Accordingly, Applicant respectfully submits that the recitation of "an expander selected from . . . a compatible protein" in Claim 13 is clear and definite to one skilled in the art.

Therefore, the rejection of Claim 13 under 35 U.S.C. §112, second paragraph, is overcome and withdrawal thereof is respectfully requested.

Claims 1-4 and 13 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by Jiang et al. (*J. Agric. Food Chem.*, Vol. 50, 5313-17, 2002).

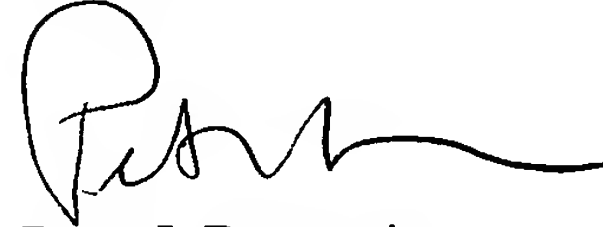
Applicant observes that the reference to Jiang et al. was published on September 11, 2002, which was within one year of the filing date (July 28, 2003) of the present application. Thus, Applicant respectfully submits that an applicant's own disclosure within the year before the application's filing date cannot be used against the applicant. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). In this regard, Applicant has also enclosed a "Katz declaration" executed by the present inventor (Jiang). In the declaration, Dr. Jiang testifies that he is the sole inventor of the subject matter described in the cited reference and the other authors of the cited reference are not co-inventors. Thus, Jiang et al. describe the inventor's own work and therefore

is not a proper reference under 35 U.S.C. § 102(a) as submitted above.

Therefore, the rejection of Claims 1-4 and 13 under 35 U.S.C. §102(a) as allegedly anticipated by Jiang et al. is overcome and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a large, stylized initial 'P'.

Peter I. Bernstein

Registration No. 43,497

Scully, Scott, Murphy & Presser, P. C.
400 Garden City Plaza, Suite 300
Garden City, NY 11530
(516) 742-4343
PIB/ZY:dg/ab

Encl.